



**FDA Division of  
Federal-State Relations  
Year in Review  
January-December 2010**

**FDA's Division of Federal-State Relations (DFSR)**

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Dear Colleague,

The previous year has been an exciting time in the Division of Federal-State Relations (DFSR). Since January 2010, DFSR's staff increased from 11 to 25 full-time employees, issued more than \$18 million in grants and cooperative agreements, gave out \$23.2 million for state contracts, and commissioned 1346 State and Local officials to assist FDA in traditional program areas such as foods and animal feeds. We have also strengthened our Public Affairs branch responsible for outreach and coordination with State and Local governments.

Prior to coming to the FDA, I worked at the State level for more than 28 years in various departments, from a field compliance officer and supervisor, program administrator and finally as a Program Director. The positive experiences of these positions have provided me with a unique state perspective. It's with this background that I can fully understand the value and impact that state and local governments bring towards working with the FDA to build a national integrated food safety system.

It is without question that the FDA and the States can equally benefit from the goal of a national food safety system with the expertise of the respective governments providing the framework.

The coming year will present DFSR with new challenges and opportunities, and we will continue to develop and grow as the new food safety legislation is implemented by FDA.

Thank you for taking the time to peruse DFSR's "Year In Review."

Sincerely,

Joseph Reardon  
Director, Division of Federal-State Relations  
U.S. Food and Drug Administration

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## **STATE GRANTS AND COOPERATIVE AGREEMENTS**

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Each year DFSR sponsors several competitive grant and cooperative agreement programs related to food safety and human health issues. These grants/cooperative agreements provide Federal-State Agencies with the opportunity to enhance or develop new and existing programs in food and feed safety and defense.

<b><i>FY10 Grant Programs</i></b>		
Program	Number of States	Amount
Food Protection Taskforces	27	\$200K
Food Emergency Response Network (FERN) -Biological -Microbiological -Radiation	34	\$10.7M
Ruminant Feed Ban Support (BSE)	12	\$3.0M
Rapid Response Teams (RRT)	9	\$4.5M
Innovative Food Defense	2	\$200K
Small Conference Grant	5	\$125K

### **Food Protection Taskforce Conference Grant**

Each state may receive up to \$10,000

Total FY 2010 \$200,000

The Food Protection Task Force Grant program supports meetings that foster communication, cooperation, and collaboration among state, local, and tribal food protection, public health, agriculture, and regulatory agencies. The meetings are designed to:

- Provide a forum for all the stakeholders of the food protection system—regulatory agencies, academia, industry, consumers, state legislators, boards of health and agriculture, and other interested parties;
- Assist in adopting or implementing food protection regulations;
- Promote the integration of an efficient statewide food protection/defense system that maximizes the protection of the public health through prevention, intervention and response; and
- Detect and contain foodborne illness early.

Funding for the Food Protection Taskforce Conference Grant increased from \$5,000 per year to \$10,000 per year in FY 2010. Ten states received the increased funding in FY10.

Alabama	Maryland	North Carolina
Colorado	Michigan	Oklahoma
Washington DC	Minnesota	Pennsylvania
Florida	Mississippi	Tennessee
Indiana	Missouri	Virginia
Kansas	Montana	Washington State
Kentucky	Nebraska	West Virginia
Louisiana	Nevada	Wyoming
Massachusetts	New Hampshire	

### **BSE/Feed Safety Program Grant**

Each state may receive up to \$250,000  
Total FY 2010 \$3,000,000

The cooperative agreements for the Ruminant Feed Ban/Feed Safety Support Program, supported by the Office of Regulatory Affairs (ORA), Division of Federal-State Relations (DFSR) in coordination with the Center for Veterinary Medicine (CVM), further enhance the infrastructure of state, territorial, and tribal animal feed safety and bovine spongiform encephalopathy (BSE) prevention programs. Under these cooperative agreements, state, territory, and tribal governments will enhance their feed safety/BSE programs to increase the ability to locate and visit companies involved in the manufacture, distribution, and transportation of animal feed as well as operations feeding ruminant animals, and to verify their compliance with the ruminant feed ban and other feed safety regulations. Funds may also be used for laboratory analysis as well as to conduct educational outreach activities and to develop materials needed to further enhance the industries' knowledge of and compliance with the ruminant feed ban and other feed safety regulations.

Three new states were awarded BSE grants in FY10.

Colorado	Kansas	New York
Florida	Kentucky	North Carolina
Illinois	Michigan	Texas
Iowa	Nebraska	Washington State

## **Food Emergency Response Network (FERN)**

The grants for Food Safety and Security Monitoring provide funding to Food Emergency Response Network (FERN) laboratories. FERN laboratories provide additional capacity for analyzing food samples in the event of food-borne disease outbreaks or other large-scale food emergency events. These samples could be foods and/or environmental samples related to foods, and will be collected by federal, state, or local agencies. Numbers of samples and scheduling of samples will be done by the FERN National Program Office in coordination with state/local laboratory authorities. Federal or state surveillance assignments will also be a source of samples for lab analysis. There are three types of FERN laboratory grants available: Microbiological, Radiological, and Chemical.

### **Microbiological**

Each state may receive up to \$250,000

Total FY 2010 \$4,000,000

Colorado	Minnesota	Pennsylvania
Florida	New Hampshire	Rhode Island
Hawaii	North Carolina	Texas
Illinois	New Mexico	Virginia
Michigan	Ohio	Washington State

### **Radiological**

Each state may receive up to \$250,000

Total FY 2010 \$1,300,000

Maryland	Texas	Wisconsin
New York	Washington State	

### **Chemical**

Each state may receive up to \$400,000

Total FY 2010 \$5,400,000

Arizona	Minnesota	Colorado
California - Davis	New Hampshire	Arkansas
Connecticut	Virginia	Nebraska
Florida	California - Richmond	Wisconsin
Iowa	Ohio	

## **Rapid Response Team**

Each state may receive up to \$500,000

Total FY 2010 \$4,500,000

The Food Protection Rapid Response Team (RRT) and Program Infrastructure Improvement Prototype Project cooperative agreements will develop, implement, exercise, and integrate an all-hazards food and foodborne illness response capability to more rapidly react to potential threats to our food supply. The RRT is designed to enhance response capabilities, drawing together partners in the food safety system including other food and feed agencies within state programs, FDA district offices, other state RRTs, and state emergency operations centers

Minnesota

Massachusetts

North Carolina

California

Florida

Michigan

Virginia

Texas

Washington State

## **Innovative Food Defense**

Each state may receive up to \$100,000

Total FY 2010 \$200,000

Food defense is a term used to describe activities associated with protecting the nation's food supply from intentional contamination. The Innovative Food Defense Program Grant encompasses 3 broad strategies in its food defense activities.

1) Awareness (Prevention/Preparedness): Increase awareness among federal, state, local, and tribal governments, and the private sector, to better understand where the greatest vulnerabilities lie and develop effective protection/mitigation strategies to shield the food supply from intentional contamination

(2) Response: Develop the capacity for a rapid coordinated response to a food borne terrorist attack

(3) Recovery: Develop the capacity for a rapid coordinated recovery from a food borne terrorist attack. Stakeholders must determine how to most effectively apply resources within this continuum of activities to best protect the food supply chain and consumers.

The specific goal of this program is to generate programs that complement, develop, or improve State and local food defense programs and which may then be applied to food defense programs nationwide.

Innovative Food Defense awards for FY10 exceeded the amounts awarded in previous years by a large margin.

Oklahoma

Riverside County, CA

### **Small Science Conference Grants (FDA-Wide Program)**

DFSR recognizes the value of supporting high quality conferences relevant to its public health issue. Grant funds are awarded to associations to host an annual conference, seminar, workshop, or symposium with a topic of interest and relevance to DFSR's mission of supporting food and feed safety.

Awards up to \$25,000

Associations currently receiving funds are: National Environmental Health Association (NEHA), Association of Food and Drug Officials (AFDO), Association of American Feed Control Officials (AAFCO), National Egg Regulatory Officials (NERO), and Conference for Food Protection (CFP).

In FY11 DFSR plans to expand the small conference grant to include additional associations.

## STATE CONTRACTS

Contact: Anita MacMullan, anita.macmullan@fda.hhs.gov

DFSR manages various sole source and fixed price contract programs with states. These contract programs benefits states with technical training, familiarity with federal requirements and more uniform enforcement of consumer laws through cooperation and coordination with FDA. The contract programs allow FDA to enlarge coverage of the Official Establishment Inventory (OEI) and also to redirect resources to other priorities.

The major 6 contract programs include Food Safety, Feed/ Bovine Spongiform Encephalopathy (BSE), Tissue Residue, Mammography Quality Standards Act (MQSA), Milk Drug, and Medical Device. These contracts are with over 145 state regulatory agencies and acquire over 25,000 inspections and data for over 4 million samples.

The purpose and focus of the programs are to:

- Leverage state regulatory resources.
- Enhance coverage of FDA regulated food and feed establishments.
- Cultivate positive working relationships with state programs

<b><i>FY10 State Contracts</i></b>			
<u>Program</u>	<u>States</u>	<u>Inspections</u>	<u>Amount</u>
Food	42*	11,392	\$9.8M
Feed	36	5,400	\$2.5M
Tissue Residue	19	260	\$318K
MQSA	46	7,373	\$9.6M
Medical Device	1	20	\$85K
Milk Residue		Data**	<u>\$105K</u>
		<b>24,445</b>	<b>\$23.2M</b>

\*45 Total Contracts- 42 States and Puerto Rico, WV and SC both have 2 contracts

\*\* Analysis of over 4 million milk residue sample analysis

### **Food Inspection Contract Program**

Under this program, inspections are performed in selected food manufacturers/processors to determine compliance with the Federal Food, Drug and Cosmetic (FD&C) Act, state law, or both; The major inspectional emphasis will be placed upon determining significant GMP, unsanitary conditions and practices which may render the food injurious to health, particularly

those involving the introduction, lack of controls, and/or growth promotion of pathogenic organisms and other conditions which may have caused food to become filthy, putrid, decomposed or contaminated with foreign objects which present a reasonable possibility of causing the contamination of food.

- Number of Contracts with states: 45 (\*45 Total Contracts- 42 States and Puerto Rico, WV and SC both have 2 contracts)
- Type of Inspections: GMP Sanitation, Seafood HACCP, Juice HACCP, LACF, and Import trace backs
- Added Idaho to the Food Inspection Program
- Added Domestic Sampling Elective
- Inspections Awarded:
  - Food Inspections: 11,392
  - Environmental Samples: 5,950
  - Domestic Samples: 60

### **Feed / BSE Inspection Contract Program**

The Medicated Feeds Program has been implemented with the assistance of the states under contract since 1973. For the last several years, states have accomplished surveillance inspections to determine whether firms manufacturing medicated feeds were in compliance with key good manufacturing practices (GMP) regulations. The Second Generation Medicated Feed Regulations, published by the FDA in 1986, set forth revised requirements concerning approval procedures for the manufacture of animal feeds containing new animal drugs. These regulations focus on high-risk drugs, i.e., carcinogens and drugs requiring withdrawal times at their lowest use level. Firms using Category II Type medicated articles to make medicated feeds are required to register with FDA and hold approved licenses. FDA is required to inspect these firms once every two years

On June 5, 1997, FDA published a final rule prohibiting the use of mammalian protein in ruminant feeds. This action was taken to prevent the spread of bovine spongiform encephalopathy (BSE) in the United States; thus, the phrase "BSE rule" to describe it. The rule, which is codified in 21 Code of Federal Regulations (CFR) 589.2000, provides for labeling, record keeping and clean out requirements for renderers, feed manufacturers, haulers of feed, and producers.

- Number of Contracts with states: 36
- Number of inspection accomplished via contracts :
  - Feed Mill GMP: 348
    - GMP Inspections conducted under the Feed Contract are for feed mills licensed in the production of Category II Type A Medicated Feeds.

- Category II drugs are animal feed drugs that require a withdrawal period. Type A drugs are drugs that are non diluted.
  - The contract states “The establishments to be inspected by the contractor as a GMP inspection will be those required to register with FDA because they manufacture medicated feeds from Category II, Type A articles which do now or will require an approved medicated feed mill license.”
- BSE: 4,663
  - Elective Inspections- 348
  - Samples- 375

### **Tissue Residue Inspection Contract Program**

Under this program, inspections of producers/owners as identified by USDA/FSIS of a tissue residue violation are conducted. The primary objectives of the inspection will be to determine and document the cause of the violative tissue residue and to educate the animal producer on ways to avoid recurrence. The inspection will obtain information on the producer's/owner's operations, drug usage, animal husbandry practices, feed delivery systems, responsibility for the violation, and disposition of any remaining animals. Inspections will include assuring compliance with the 21 CFR 589.2000, "Substance Prohibited from Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed", commonly known as the "BSE Rule".

- Number of Contracts with states: 19
- Number of inspection accomplished via contracts: 260
- Obtain state assistance in reducing the number and severity of drug residues in the edible tissue of food animals
- 2010 Contract Budget Total: \$318,000

### **MQSA Inspection Contract Program**

The Mammography Quality Standards Act (MQSA) of 1992, was signed into law on October 27, 1992. The intent of the Act is to ensure that women receive high quality mammography for early breast cancer detection by requiring the establishment of a federal certification and inspection program for mammography facilities. The Act authorizes FDA to obtain state and local assistance in enforcing the MQSA requirements including annual inspections of all certified mammography facilities.

- Number of Contracts with states: 46
- Number of inspection accomplished via contracts: 7,373
- 2010 Contract Budget Total: \$9.6M

### **National Milk Drug Residue Database**

The Food and Drug Administration (FDA) and the states share responsibility for assuring that the nation's milk supply is safe and not contaminated with harmful residues of drugs. This task is accomplished through a cooperative agreement between FDA and the states under the National Conference on Interstate Milk Shipments (NCIMS).

The National Milk Drug Residue Database was implemented in cooperation with the National Conference on Interstate Milk shipments, an organization of state officials responsible for the Grade A fluid milk production in this country. The contract is part of an effort to improve control over drug residues in the milk supply, and to be able to demonstrate the amount and results of collective industry and government milk testing.

- Number of Contracts: 1

## **COMMISSIONING PROGRAM**

Contact: Anna Finn, [anna.finn@fda.hhs.gov](mailto:anna.finn@fda.hhs.gov)

The Commissioning Program was developed to make inter-agency cooperation more effective and, hence, increase the amount of protection afforded to the American consumer. The program was designed to utilize the potential of state and local officials to perform specifically designated functions that are subject to Federal jurisdiction, e.g., to conduct examinations, inspections, and investigations; to collect and obtain samples; copy and verify records; and receive and review official FDA documents. Any officer or employee of a state, territory or a political subdivision thereof can be commissioned as an officer of the Department of Health and Human Services. Each commission is issued for a period of five years. Towards the end of this period, FDA will review each commission and determine whether it should be renewed. Depending on the scope of the commission, the receiving official might receive pocket credentials and a wall certificate or just a wall certificate.

There are many possible reasons to grant an FDA Commission including: to enable the official to conduct inspections and collect samples under a Partnership Agreement or FDA Contract, even if their own state/local laws do not provide such authority; to enable the official to operate under the Federal FD&C Act, as well as their own state/local authority whichever best serves the situation; and to enable the official to see and review certain pieces of FDA information normally considered confidential and not releasable to the general public. The ability to solicit the advice of and to tap the expertise of state and local counterparts, as well as the ability to share regulatory activities, without having to make any public disclosure of the information, is a major advantage of the program. This practice has found increasing use during the last few years.

The current policies and procedures were developed, and refined over the years, by FDA to grant specific authority in a specific program area in a designated state to state and local officials pursuant to the following laws: Section 702(a)(1)(A) of the Federal Food, Drug, and Cosmetic Act; Section 360 E(2) of the Public Health Service Act; and authority delegated to the Commissioner of Food and Drugs by the Secretary of Health and Human Services under 21 CFR 5.35.

In 2010, the commissioning process for pocket credentials was updated to be in line with what is required of FDA employees. In compliance with the homeland security presidential directive 12, all federal employees and contractors must undergo a minimum level five public trust background investigation. The Division of Federal State Relations is working closely with the Office of Security Operations to facilitate and adjudicate all the background investigations for the state and local commissioned officials.

The background investigations consist of 3 parts:

- Criminal
- Credit
- Reference/ Sit Down Interview with OPM Investigator

Currently there are 1,060 state and local commissioned officials with the FDA in traditional program areas. State and local officials currently hold FDA commission in "traditional" areas such as: animal feeds; foods; drugs; medical devices, eggs, BSE etc.

As a result of the recent increased jurisdiction over tobacco, the commissioning program has expanded to include the program area. DFSR currently oversees the commissioning program for the Center of Tobacco Products (CTP) and works as liaison between CTP and Office of Security Operation, there are 15 states with commissioned officials in the tobacco program.

## **20.88 CONFIDENTIALITY AGREEMENTS**

Contact: Anna Finn, [anna.finn@fda.hhs.gov](mailto:anna.finn@fda.hhs.gov)

The FDA published a regulation on sharing non-public information with State and local officials under 21 Code of Federal Regulations (CFR) § 20.88 as a Final Rule in the December 8, 1995 Federal Register (60 CFR 63372). The rule allows the FDA to share certain confidential Agency records on a discretionary basis with State and local government officials who perform counterpart functions to FDA as part of cooperative law enforcement of regulatory efforts provided that certain conditions are met. Such disclosures under this provision are never mandatory and each State or local government request would be processed only after duly considering FDA's concerns for confidentiality, the requester's need for the information, and the benefit to the public health that may result from such sharing.

After considering the Federal-State Food Safety Initiative, the goals of that program and the need to more rapidly share food protection information between the FDA and State and local government agencies, the current procedures under 21 CFR § 20.88 were streamlined so non-public information about food protection issues could be efficiently and effectively shared with local and State government officials.

DFSR maintains the National database of State and local government agencies that have signed 20.88 confidentiality commitment agreements. This agreement is limited to the FDA's streamlined program to share non-public food safety information. Under the streamlined procedures, FDA can rapidly share non-public information, including confidential commercial information and FDA pre-decisional information, with local and State agencies responsible for food inspection programs and laboratories regarding food-related product information, inspections, enforcement actions, and foodborne illness investigation data and trace-back information.

All agreements expire on December 31 and are renewed for a period of three years. Original signatures are required by all persons who receive non-public information.

### **2010**

- Individuals who have signed a 20.88 database- over 900
- State agencies who have current 20.88 agreements with FDA (agreement period 2010-2013)- 47

## **REPORTABLE FOOD REGISTRY**

Contact: Anna Finn, [anna.finn@fda.hhs.gov](mailto:anna.finn@fda.hhs.gov)

The Reportable Food Registry (RFR) was established by section 1005 of the Food and Drug Administration Amendments Act of 2007 (Pub. L.110-085) to provide a reliable mechanism to track patterns of adulteration in food in order to support efforts by FDA to target limited inspection resources to protect the public health. The RFR covers all foods regulated by FDA except infant formula and dietary supplements.

The RFR requires a responsible party to file a report through the RFR electronic portal when there is a reasonable probability that the use of, or exposure to, an article of food will cause serious adverse health consequences or death to humans or animals. Such foods are "Reportable Foods."

DFSR oversees the contact database of state and local commissioned officials who have been identified as state RFR contacts. The state's contacts who receive notifications of RFR incidents are all FDA commissioned officials.

In 2010, the RFR incident notification system was updated to automatically distribute email notifications to the districts and states affected by the incident simultaneously. By receiving the RFR reports at the same time, our state counterparts now have a reliable mechanism to track patterns of adulteration in food in order to target inspection resources to protect the public health.

The states and district counterparts work collaboratively to develop a response to each RFR incident. In some cases the state or FDA will take the lead on response, in others cases a joint response will be conducted by FDA and the state counterparts.

## **PUBLIC AFFAIRS**

Contact: Cathy McDermott, catherine.mcdermott@fda.hhs.gov

The DFSR Public Affairs Branch informs and interacts with stakeholders about DFSR and FDA activities and initiatives, and coordinates communications with stakeholders throughout the agency. The branch exists to promote the programs, services, and initiatives within the FDA's DFSR to its internal and external stakeholders.

### **Public Affairs Goals**

DFSR's Public Affairs Branch aims to:

- Promote financial agreements funded through DFSR
- Develop and implement communications platforms, programs, and strategy
- Expedite the communication of information between Federal and State partners
- Develop and build advocacy of DFSR programs and initiatives
- Increase stakeholder awareness and education of DFSR role and function
- Support the mission of DFSR

### **Produce Rule Listening Sessions**

The demand for fresh, safe produce prompted the FDA to begin thinking about a produce rule that provides guidance to the produce community on production, transportation, and storage of fruits and vegetables. Before the rulemaking process began at FDA's Center for Food Safety and Applied Nutrition (CFSAN), the FDA Office of Foods and DFSR put together a series of produce rule listening sessions around the country to elicit feedback from producers, distributors, wholesalers, and regulators on what these guidelines should look like.

In the spring of 2010, DFSR facilitated meetings in San Antonio, TX (April 27); Portland, OR (May 5); and Harrisburg, PA (May 13). At each session, the Office of Foods and CFSAN heard from a wide range of stakeholders, from small farmers and producers to national distributors and wholesalers. Participants also had the opportunity to visit some local farms at each location to get a better sense of the size and scale the operations that would be affected by a potential FDA produce rule. The produce rule listening sessions, facilitated by DFSR, garnered more than 700 submissions for feedback on what should be included in the guidelines.

### **CAP Meeting**

DFSR invited the Council of Association Presidents (CAP) to FDA's White Oak campus in May 7, 2010, to discuss cooperation and outreach with state associations involved in food and feed safety. FDA Deputy Commissioner for Foods Michael Taylor and the CAP representatives talked about increasing stakeholder involvement in the FDA's food safety system and talked about what the potential food safety bill would look like. DFSR will explore the possibility of

facilitating bi-annual FDA-CAP meetings, a MFRPS conference, and serving as liaisons between FDA and CAP association representatives.

Current CAP members include:

American Association of Feed Control Officials  
Association of Food and Drug Officials  
Association of Public Health Laboratories  
Association of State and Territorial Health Officials  
Council of State and Territorial Epidemiologists  
National Association of City and County Health Officials  
National Association of Local Boards of Health  
National Association of State Animal Health Officials  
National Association of State Departments of Agriculture  
National Environmental Health Association  
U.S. Animal Health Association

## **50-State Meeting**

On August 17-19, 2010, the Food and Drug Administration (FDA) held a 50-State workshop, entitled “A United Approach to Public Health,” in Denver, Colorado. The workshop attendees brought diverse perspectives from federal, state, local, and territorial government agencies to ensure a mix of state and local perspectives. Officials from all 50 states, including five U.S. territories, provided expertise in food, feed, epidemiology, laboratory, animal health, and environmental and public health. Several federal agencies, including FDA, the Centers for Disease Control and Prevention (CDC), the U.S. Department of Agriculture’s (USDA) Food Safety and Inspection Service (FSIS), Department of Defense (DOD), Department of Homeland Security (DHS), Environmental Protection Agency (EPA), and Indian Health Service (IHS) were represented.

The workshop highlighted the progress of the Partnership for Food Protection (PFP) workgroups, provided an update on current legislative issues, and offered an opportunity for discussion and input on building an Integrated Food Safety System (IFSS). The majority of participants’ time was spent in small group sessions, the intent of which was for participants to engage in strategic-level discussions that will shape the future direction of the Integrated Food Safety System.

The workshop was designed to provide a setting for the state, local, and territorial stakeholders to apply their expertise across multiple public health disciplines with a role in food safety to address the challenges of a growing global food supply. The participants were tasked with identifying and developing a series of action items and recommendations to further the development and implementation of an Integrated Food Safety System. Participants were split into groups to provide advice and recommendations on addressing challenges and conflict, integrating response efforts, conducting joint investigations, improving communication, and

measuring outcomes. The breakout session groups prioritized those recommendations. On the third and final day of the conference, representatives from each breakout session presented the top recommendations to the general session. In addition to these breakout groups, participants also examined the current resource crisis and its consequences and the benefits of sharing resources to maintain the public health infrastructure, with the goal of developing unified talking points to take to policy makers at all levels.

The Partnership for Food Protection Coordinating Committee is currently looking at the recommendations made by the 50-state breakout groups and are evaluating how best to integrate the suggestions to improve the design and implementation of an Integrated Food Safety System.

### **Taskforce Broadcast**

The Food Protection Taskforce Conference Grant program, funded by DFRS, supports meetings that foster communication, cooperation, and collaboration among all stakeholders of the food protection system: regulatory agencies, academia, industry, consumers, state legislators, boards of health and agriculture, in an effort to enhance food safety and defense capabilities. Twenty-seven states currently receive the grant award up to \$10,000, including the addition of five new states in FY 2010. In the future, DFRS hopes to have an FDA funded taskforce in every state.

Based on feedback from the current taskforce grant recipients, DFRS learned there is a need for more communication with other taskforces and FDA to be able to share best practices, ask questions, get ideas, and discuss issues.

To address this need, DFRS hosted a live webcast for members of the Food Protection Taskforces on December 2, 2010 from 2-3:30 PM EST. Participants included Dara Corrigan, Associate Commissioner for Regulatory Affairs, Joe Reardon, Director, Division of Federal-State Relations, and Mike Taylor, Deputy Commissioner for Foods and four representatives of Food Protection Taskforces from Michigan, North Carolina, Tennessee, and Indiana. The state participants discussed some key areas of concern for the taskforces including the value these taskforces bring to a state's food safety system, how taskforces can be structured, and the expectations of the taskforce members.

The Taskforces were encouraged to schedule their meetings around the broadcast and view as a group. The webcast was well attended with 25 of the 27 taskforces agreeing to host the webcast in conjunction with their meeting. In addition, there was an excess of 400 direct connects with various size audiences.

## **MANUFACTURED FOOD REGULATORY PROGRAM STANDARDS**

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The FDA, along with selected state program managers, worked to develop a set of standards that could be used by the states as a guide for continuous improvement for state food manufacturing programs. These standards were designed to be used as a foundation for creating, implementing, documenting, and operating a state food manufacturing program. States choose to implement the *Manufactured Food Regulatory Program Standards* (MFRPS) as an option under their state food contracts.

States are currently paid \$5,000.00 a year to implement the MFRPS and for each year they continue in the program. The first contractual obligation for the newly implementing state is to do a self-assessment of their food manufacturing program against the MFRPS and develop an improvement plan for program areas where the state feels it does not meet the intent of the standard(s). The next step is to participate in an FDA assessment of the state's self-assessment and improvement plan. This assessment is done between the twelfth and eighteenth month of participation. A second FDA assessment is done around the thirty-six month participation mark to ensure the state food program is on track with their improvement plan. The first two assessments are led by DFSR and involve individuals from the FDA District offices. At the sixty month mark an external audit is conducted of the state food manufacturing program for full compliance with the MFRPS. This sixty month audit is paid for by FDA, but is not conducted or led by FDA.

### **The Development and Integration Branch Team**

DFSR has created the Development and Integration Branch (D&I Branch) to assist states with the MFRPS. This branch includes eight positions. Six of these positions are co-located in the field and two located in Rockville. The six standard specialists are located in six regional offices and assist states with: Self-assessments, gap analysis, technical guidance to promote compliance with the MFRPS, promote sharing and exchange of best practices related to implementation of the MFRPS, and development and improvement of the Standard. The standards specialists are: Angela Kohls, working out of the USDA Farm Agency Service (FAS) office in Manhattan, KS; Tressa Madden, working out of the FDA Oklahoma City Resident Post; Travis Goodman, working out of the Indianapolis Resident Post; Guy Delius, working out of the Louisville, KY, Resident Post; Priscilla Neves, working out of the New England District Office in Stoneham, MA; and Ellen Laymon, working out the Beaverton Resident Post, located in Portland, OR.

## **MFRPS Outreach**

The DFSR Development and Integration Branch developed a two and a half-day MFRPS self-assessment review process to help states prepare for their initial 12 month program assessment verification audit by FDA. Two pilot meetings were conducted in Rockville, MD, and Oklahoma City, OK, in October involving approximately 34 participants from 12 state programs, seven districts, and DFSR and Division of Field Science (DFS) headquarters.

The meetings provided states the opportunity to review the accuracy of their self-assessment and improvement plans as well as share best practices and tools used in the implementation of the MFRPS. They also provided input to address challenges and barriers. The meeting facilitation strategy also provided the Districts with the opportunity to improve federal-state integration initiatives relative to communication, sharing of inspection and enforcement activities, and work planning. Feedback from the meetings has been very positive validating the need for DFSR to provide MFRPS training to states new to MFRPS as well as to encourage dialogue and sharing of information between states and districts.

In addition to regional meetings, the Development and Integration Branch created a MFRPS Workgroup meeting space on FoodSHIELD to facilitate communication and collaboration between states and FDA relative to the development and implementation of the MFRPS. Membership and participation on FoodSHIELD is free. Using this communication vehicle, the Development and Integration Branch initiated monthly outreach calls to highlight application of specific Standards within the MFRPS, and to address user questions. Monthly topics presented in 2010 included:

- MFRPS Overview
- Introduction to FoodSHIELD
- Development of pre-assessment tools
- Standard 2: Training
- Standard 7: Industry and Community Relations

The outreach relative to MFRPS is an important part of the national Integrated Food Safety System (IFSS). MFRPS establishes a uniform foundation for the design and management of State programs responsible for the regulation of food plants. The elements of the program describe best practices of a high-quality regulatory program. Achieving conformance with them will require comprehensive self-assessment on that part of a State program and will encourage continuous improvement and innovation. The programs standards are comprised of ten standards that establish requirements for the critical elements of a regulatory program designed to protect the public from foodborne illness and injury. The development and implementation of these standards will help Federal and State programs improve the safety and security of the American food supply.

A complete overview of MFRPS can be viewed on DFSR's website.

## **RAPID RESPONSE TEAMS (RRT)**

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### **Funding:**

Awards up to \$500,000 per recipient per year

DFSR is working with pilot programs in nine states through the Food Protection Rapid Response Team (RRT) and Program Infrastructure Improvement Prototype Project cooperative agreement to strengthen state food program infrastructure and to develop capabilities for responding to potential threats to the food/feed supply, from farm to fork. The RRT project engages partners throughout the food safety system, including state departments of agriculture, health, and emergency; FDA field offices; laboratories; local health departments; and other federal partners and national initiatives to identify, implement, and share best practices in emergency response (using Incident Command System (ICS) concepts) for food/feed incidents.

### **States implementing programs:**

California  
Florida  
Massachusetts  
Michigan  
Minnesota  
North Carolina  
Virginia  
Texas  
Washington State

### **Accomplishments:**

The RRT project has engaged state partners to work with FDA to use RRT funds to strengthen state food safety programs, building program infrastructure through implementation of the Manufactured Food Regulatory Program Standards (MFRPS) and improving rapid response by exploring and enhancing key response capabilities. RRT pilots have completed a variety of work, with even common tasks varying for each state's unique situation. Examples include completing MFRPS self-assessments and improvement plans, developing software to support interagency information sharing, and training team members in food outbreak response (e.g. Epi-Ready) and the ICS.

In July 2010, the RRTs met in New Orleans for the annual face-to-face meeting. There, the nine RRTs shared their project successes with each other and all meeting participants discussed project challenges, areas for collaboration, and project priorities. Following the meeting, the RRTs identified priority topics to develop as part of an RRT "Playbook"; this playbook would present best practices in food/feed incident response in a way that can be understood,

customized, and implemented by any other state (e.g. guides, templates, and examples). Federal and state members of the nine RRTs formed working groups to address the following topics: Food Emergency Response Plans, Communication Standard Operating Procedures (SOPs), Training, Working with other Agencies, Using Incident Command System in the response, Traceback, Joint Investigations, and Ongoing Activities of the RRTs. In December, the working groups completed draft models for each of the eight topics for the playbook.

As this pilot project continues, the RRTs will work to further develop this playbook and other tools and concepts that will not only improve the response systems in these nine states, but will also benefit food safety and defense in non-RRT states, ultimately strengthening the national system as a whole.

## **QUALITY MANAGEMENT SYSTEM**

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The implementation of the ORA Quality Management System (QMS) is a result of the ORA Revitalization Initiative. The ORA QMS is geared toward embedding quality in all areas of ORA's products, processes, and services.

ORA's QMS goals are to ensure that work products and services are fit for their intended use, and that resources and processes are aligned with ORA's strategic direction.

DFSR is deeply involved in the implementation of the ORA QMS and is in the process of facilitating the QMS computer-based online training session (MP120). To date, 100 percent of DFSR's personnel have completed the ORA QMS training of the nine core procedures and 90 percent have completed the MP120-Orientation to ORA QMS training. DFSR will be assessed in the first quarter of CY 2011 to determine how well the division has implemented the nine core procedures that serve as the framework for the ORA QMS.

Prior to the initiation of the QMS in DFSR (Spring 2010), no formalized documents or procedures were being utilized. To date, three have been implemented and 24 are in draft form. Three of the documents are evaluation forms that assist DFSR in meeting or exceeding our customer's needs and expectations and the ultimate goal of continual improvement. Complaints and other feedback are also captured and will be used in the long-term compilation and analysis of trends and concerns.

In an effort to gauge current performance and detect opportunities that will enable DFSR to operate more efficiently and effectively, two quality indicators have been identified and are being monitored for tracking and trending. They include the DFSR Requisition Process and the objective to have 95 percent or greater requisitions processed without error and the Manufactured Food Regulatory Program Standards (MFRPS) Evaluation Form with the objective to obtain an overall satisfactory survey rating of 80 percent or greater on the monthly MFRPS conference call.

Prior to the initiation of the QMS, quality indicators were not being tracked or measured in DFSR. The DFSR Requisition Process indicator will assist in ensuring requisition forms are accurately entered thereby guaranteeing the correct amount of funding is obligated to the contractor and the amount of rework is reduced. The objective of the MFRPS Evaluation Form is to assist the DFSR Development & Integration Branch to better serve the States. The Quality System Manager randomly selects States to evaluate and critique the MFRPS monthly call. Data obtained from this feedback is used to identify areas in which DFSR is performing well and areas of the program that can benefit from improvement.

DFSR will continue to monitor and improve its processes with the assistance of the ORA Quality Management System.